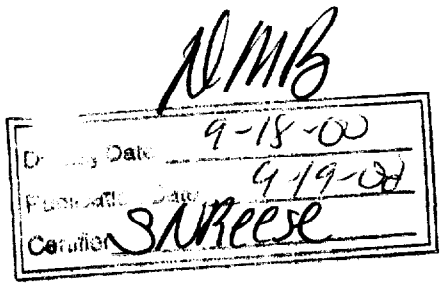

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 203 and 205

[Docket No. 92N–0297]

Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administration Procedures; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Announcement of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing to discuss certain requirements of the final rule implementing the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992 (PDA) and the FDA Modernization Act of 1997 (Modernization Act), which published in the **Federal Register** of December 3, 1999 (64 FR 67720), (hereinafter referred to as the PDMA final rule). The purpose of the hearing is to elicit comment from interested persons, including professional groups and associations, the regulated industry, health care professionals, and consumers, on the potential impact of certain requirements in the PDMA final rule relating to wholesale distribution of prescription drugs by distributors that are not authorized distributors of record, and distribution of blood derivatives by entities that meet the definition of a ''health care entity'' in the PDMA final rule. The agency will use information obtained from the hearing and the comments to this document to determine what steps, if any, should be taken to modify the requirements in the PDMA final rule.

DATES: The public hearing will be held on Friday, October 27, 2000, from 8:30 a.m. to 4:30 p.m. Submit written notices of participation and comments for consideration at the hearing to the

docket number listed in the heading of this document by October 13, 2000.[1] Written comments will be accepted after the hearing until November 20, 2000.

ADDRESSES: The public hearing will be held at 5630 Fishers Lane, rm. 1066, Rockville, MD 20852. Submit written notices of participation to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should also be submitted to the Dockets Management Branch (address above). Transcripts of the hearing will be available for review at the Dockets Management Branch (address above).

FOR FURTHER INFORMATION CONTACT: Anne M. Henig, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5410.

SUPPLEMENTARY INFORMATION:

I. Background

A. Legislative and Regulatory Requirements for Distribution of Prescription Drugs by Unauthorized Distributors

PDMA, as amended by the PDA, amended sections 301, 303, 503, and 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331, 333, 353, 381) to, among other things, establish requirements for the wholesale distribution of prescription drugs; and to prohibit, with certain exceptions, the sale or offer to sell prescription drugs that have been purchased by a hospital or other health care entity or that have been donated or supplied at a reduced price to a charitable organization.

Section 503(e)(1)(A) of the act states that each person who is engaged in the wholesale distribution of a prescription drug who is not the manufacturer or an authorized distributor of

[1]Until recently, two dockets were being used to receive comments on issues related to PDMA. One docket, the docket established in 1988, will no longer be used. For simplicity, all comments related to any issues involving PDMA should be forwarded to the docket listed in the heading of this document.

record for the drug must, before each wholesale distribution of a drug, provide to the person receiving the drug a statement, also known as a drug ''pedigree, (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of the drug, including the date of the transaction and the names and addresses of all parties to the transaction. Section 503(e)(4)(A) of the act states that, for the purposes of section 503(c), the term ''authorized distributors of record'' means those distributors with whom a manufacturer has established an ''ongoing relationship'' to distribute the manufacturer's products.

In the PDMA final rule, the agency published regulations in part 203 (21 CFR part 203) implementing these and other provisions of PDMA. Section 203.50 implements section 503(e)(1)(A) of the act and requires that, before the completion of any wholesale distribution by a wholesale distributor of a prescription drug for which the seller is not an authorized distributor of record to another wholesale distributor or retail pharmacy, the seller must provide to the purchaser a statement identifying each prior sale, purchase, or trade of the drug. The identifying statement must include the proprietary and established name of the drug, its dosage, the container size, the number of containers, lot or control numbers of the drug being distributed, the business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer, and the date of each previous transaction. Section 203.3(b) defines ''authorized distributor of record'' as a distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products. ''Ongoing relationship'' is defined in § 203.3(u) to mean an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer's products for a period of time or for a number of shipments. If the distributor is not authorized to distribute a manufacturer's entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute.

Thus, the PDMA final rule requires unauthorized distributors (i.e., those distributors who do not have a written authorization agreement) to provide a drug statement, or pedigree, to purchasers

showing the entire prior sales history of the drug back to the first sale by the manufacturer. As discussed in the preamble to the PDMA final rule (64 FR 67720 at 67747), manufacturers and authorized distributors of record are not required to provide an identifying statement when selling a drug, although the agency encouraged them to do so voluntarily to permit unauthorized distributors to continue to be able to purchase products from them.[2]

The provisions in the PDMA final rule related to wholesale distribution of prescription drugs by unauthorized distributors (i.e., §§ 203.3(u) and 203.50) were adopted from the provisions in the proposed rule published in the **Federal Register** of March 14, 1994 (59 FR 11842), and are essentially the same as the proposed provisions, except the definition for ''ongoing relationship'' in the proposed rule was revised to eliminate certain requirements.[3] The agency received two comments on the proposed definition of ongoing relationship and one comment on proposed § 203.50, and responded in detail to those comments in the preamble to the PDMA final rule (see 64 FR 67720 at 67727, 67728, and 67747).

B. Legislative and Regulatory Requirements Restricting Distribution of Blood Derived Prescription Drug Products by Health Care Entities

Section 503(c)(3)(A) of the act states that no person may sell, purchase, or trade, or offer to sell, purchase, or trade, any prescription drug that was purchased by a public or private hospital or other health care entity. Section 503(c)(3)(B) of the act states several exceptions to section 503(c)(3)(A), none of which are relevant to this discussion. Section 503(c)(3) of the act also states

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[2] An unauthorized wholesale distributor that purchases a product from a manufacturer or authorized distributor of record without an identifying statement showing the prior sales of the drug could not provide an identifying statement to its purchasers and, therefore, could not conduct further wholesale transactions of the drug in compliance with § 203.50.

[3] The proposed rule defined ''ongoing relationship'' to require a written agreement and, in addition, the following two requirements that were eliminated in the final rule: (1) That a sale be completed under the written agreement and (2) that the distributor be listed on the manufacturer's list of authorized distributors.

that ''[f]or purposes of this paragraph, the term 'entity' does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law * * *.''

Sections 203.20 of the PDMA final rule provides, with certain exceptions, that no person may sell, purchase, or trade, or offer to sell, purchase, or trade any prescription drug that was purchased by a public or private hospital or other health care entity or donated or supplied at a reduced price to a charitable institution. In § 203.3(q) of the PDMA final rule, ''Health care entity'' is defined as meaning any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or wholesale distributor. Under both the act and the PDMA final rule, a person could not simultaneously be a health care entity and a retail pharmacy or wholesale distributor. Thus, under the PDMA final rule, blood centers functioning as health care entities could not engage in wholesale distribution of prescription drugs, except for blood and blood components intended for transfusion, which are exempt from PDMA under § 203.1 of the PDMA final rule. Blood and blood components include whole blood, red blood cells, platelets, and cryoprecipitated antihemophilic factor, which are prepared by blood banks who collect blood from donors and separate out the components using physical or mechanical means. Blood derivatives are derived from human blood, plasma, or serum through a chemical fractionation manufacturing process. Examples of blood derivative products include albumin, antihemophilic factor, immune globulin, and alpha-1 anti-tripsin. As discussed in the preamble to the PDMA final rule in response to comments (64 FR 67720 at 67725 through 67727), blood derivative products are not blood or blood components intended for transfusion and therefore could not be distributed by health care entities, including full service blood centers that function as health care entities, after the final rule goes into effect. The agency received several comments on the proposed rule objecting to the applicability of the sales restrictions to the sale of blood derivatives by blood centers that function as health care entities, and responded in detail to those comments (see 64 FR 67720 at 67726).

C. Events Leading to the Delay of the Effective Date; Need for the Public Hearing

After publication of the PDMA final rule, the agency received letters and petitions and had other communications with industry, industry trade associations, and members of Congress objecting to the provisions in §§ 203.3(u) and 203.50 On March 29, 2000,[4] the agency met with representatives from the wholesale drug industry and industry associations. The meeting participants discussed their concerns with both: (1) The requirement in § 203.3(u) that there be a written authorization agreement between a manufacturer and distributor for the distributor to be considered an authorized distributor of record under § 203.3(b), and (2) the requirement in § 203.50 that unauthorized distributors provide a pedigree showing all prior sales going back to the manufacturer.

The meeting participants asserted that manufacturers are unwilling to enter into written authorization agreements with the majority of smaller wholesalers. As a result, these wholesalers cannot become authorized distributors of record for the drugs they sell. The meeting participants also said that smaller wholesalers cannot obtain the required pedigree showing all prior sales of the drugs they purchase for sale because a large portion of these drugs are purchased from authorized distributors who are not required to provide a pedigree and who are unwilling to voluntarily provide them. The meeting participants asserted that authorized distributors will not voluntarily provide pedigrees when they sell drugs to unauthorized distributors because it would require them to change their warehouse and business procedures, which would entail additional effort and expense.

The meeting participants asserted that implementation of the PDMA final rule will prevent over 4,000 smaller, unauthorized distributors from distributing drugs to their customers and may put them out of business, at least with respect to their prescription drug wholesale business. They also asserted that because many of their customers are smaller retail outlets that are not served

[4] In a document published in the **Federal Register** of May 3, 2000 (65 FR 25639 at 25640), the agency incorrectly stated that this meeting occurred in early February 2000.

by larger distributors, implementation of the PDMA final rule may leave certain markets for prescription drugs, and ultimately consumers for prescription drugs, underserved.

In addition to the meeting discussed above and other informal communications that FDA has had with industry, industry associations, and Congress, FDA received a petition for stay of action requesting that the relevant provisions of the PDMA final rule be stayed until October 1, 2001. That petition was supported by numerous letters submitted to the docket from entities that would be considered unauthorized distributors under the PDMA final rule. The agency also received a petition for reconsideration from the Small Business Administration (SBA) requesting that FDA reconsider the PDMA final rule and suspend its effective date based on the projected severe economic impact it would have on over 4,000 small businesses. The petitions argued that the requirement for a written agreement in § 203.3(u) is unreasonable because manufacturers are not willing to enter into such agreements with the majority of smaller distributors. The petitions also asserted that authorized wholesalers are not now able and could not provide, at a reasonable cost, a pedigree to their unauthorized distributor customers that meets the requirements of § 203.50 of the PDMA final rule. The SBA petition asserted that, if the effective date of the PDMA final rule is not stayed, drug products now in the inventory of wholesalers will have to be cleared and new orders will have to cease or be severely limited to comply with the PDMA final rule's December 4, 2000, effective date, with corresponding disruptions in the distribution of drugs possible by summer 2000.

In addition to the submissions on wholesale distribution by unauthorized distributors, the agency has received several letters on, and has held several meetings to discuss, the implications of the final regulations on blood centers that distribute blood derivative products and provide health care as a service to the hospitals and patients they serve. The blood center industry asserts that the regulations and, particularly the definition of ''health care entity,'' will severely inhibit their ability to provide full service care to the detriment of client hospitals and the patients they serve,

and may disrupt the distribution of these products to the public. The agency also received a letter from Congress on this issue.

Based on the concerns expressed by industry, industry associations, and Congress about implementing §§ 203.3(u) and 203.50 by the December 4, 2000, effective date, the agency published a document in the **Federal Register** of May 3, 2000 (65 FR 25639), delaying the effective date for those provisions until October 1, 2001 (the May 2000 document). In addition, the May 2000 document delayed the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities until October 1, 2001. The May 2000 document also reopened the administrative record and gave interested persons until July 3, 2000, to submit written comments. As stated in the May 2000 document, the purpose of delaying the effective date for these provisions was to give the agency time to obtain more information about the possible consequences of implementing them and to further evaluate the issues involved.

On May 16, 2000, the House Committee on Appropriations (the Committee) stated in its report accompanying the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2001 (report 106–619) that it supported the ''recent FDA action to delay the effective date for implementing certain requirements of the Prescription Drug Marketing Act until October 1, 2001 and reopen the administrative record in order to receive additional comments.'' In addition, the Committee stated that it ''believes the agency should thoroughly review the potential impact of the proposed provisions on the secondary wholesale pharmaceutical industry.'' The Committee directed the agency to provide a report to the Committee by January 15, 2001, summarizing the comments and issues raised and agency plans to address the concerns.

In light of the complexity of the issues involved and the potentially serious economic and public health consequences that implementation of the relevant provisions of the PDMA final rule may have, the agency believes that it is appropriate to hold a public meeting to solicit information from, and the views of, interested persons, including professional groups and associations, the

regulated industry, health care professionals, and consumers. This will help to develop an adequate factual basis that the agency can use to determine whether it is in the public health interest to take steps to modify or change the requirements in the PDMA final rule.

II. Scope of the Hearing

The PDMA final rule provisions discussed in this document raise many complex economic and public health issues. To promote a more useful discussion at the public hearing, FDA has developed the following list of questions, which are of specific interest. This list is not intended to be exclusive, and presentations and comments answering other questions or addressing other issues, to the extent that they are pertinent to the PDMA final rule provisions discussed in this document, are encouraged.

A. Questions on Distribution of Prescription Drugs by Unauthorized Distributors

1. How does the PDMA final rule, as published, affect the ability of unauthorized distributors to engage in drug distribution, i.e., what specific requirements would be difficult or impossible for unauthorized distributors to meet? Why?

2. If the PDMA final rule diminished the ability of unauthorized distributors to engage in drug distribution, what effect would this have on the drug distribution system? What, if any, adverse public health consequences would result? What would be the economic costs to manufacturers, distributors (authorized and unauthorized), and consumers of drugs?

3. If the act were amended by Congress to delete the requirement for provision of a drug pedigree by unauthorized distributors, would there be an increased risk of distribution of counterfeit, expired, adulterated, misbranded, or otherwise unsuitable drugs to consumers and patients?

4. If the act were amended by Congress to require authorized distributors to provide a pedigree, what types of additional costs and burdens would they incur?

5. Could specific changes be made to the information that is required under § 203.50 to appear on a pedigree to make it more practical, from an authorized distributor's standpoint, to voluntarily provide a pedigree? Would use of a standardized government form be helpful?

6. If actual sales by a manufacturer to a distributor were used by FDA as the only criterion to determine whether an ongoing relationship exists between them (and as a result, whether the distributor is an authorized distributor of record), would it result in more distributors being authorized than if a written authorization agreement is required? What other types of criteria might be used by FDA to make this determination?

B. Questions on Distribution of Blood Derivatives by Blood Banks and Other Health Care Entities

1. What distribution systems are available for blood derived products? Do these distribution systems differ from those for other types of prescription drugs? If so, how?

2. What effect would the PDMA final rule, as published, have on the distribution system for blood derived products? What, if any, adverse public health consequences would result? What would be the economic costs to manufacturers, distributors, and consumers of blood derived products?

3. If blood derived products were excluded from the sales restrictions (i.e., if such products were permitted to be sold by health care entities), would there be an increased risk of distribution of counterfeit, expired, adulterated, misbranded, or otherwise unsuitable blood derived products to consumers and patients? Why or why not?

4. Do manufacturers of blood derived products provide these products to health care entities, particularly those that are also charitable organizations, at a lower price when compared to other customers? Do manufacturers sell these products to charitable or for profit health care entities with the understanding that the products will be used for patients of the purchasing health care entity and will not be resold to other health care entities, distributors, or retail pharmacies?

III. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs (the Commissioner) is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The presiding officer will be the Commissioner or her designee. The presiding officer will be accompanied by a panel of FDA employees with relevant expertise.

Persons who wish to participate in the part 15 hearing must file a written notice of participation with the Dockets Management Branch (address above) prior to October 13, 2000. To ensure timely handling, any outer envelope should be clearly marked with the Docket No. 92N–0297 and the statement "FDA PDMA Hearing." Groups should submit two copies. The notice of participation should contain the person's name; address; telephone number; affiliation, if any; the sponsor of the presentation (e.g., the organization paying travel expenses or fees), if any; brief summary of the presentation; and approximate amount of time requested for the presentation. The agency requests that interested persons and groups having similar interests consolidate their comments and present them through a single representative. FDA will allocate the time available for the hearing among the persons who file notices of participation as described above. If time permits, FDA may allow interested persons attending the hearing who did not submit a written notice of participation in advance to make an oral presentation at the conclusion of the hearing.

After reviewing the notices of participation and accompanying information, FDA will schedule each appearance and notify each participant by telephone of the time allotted to the person and the approximate time the person's oral presentation is scheduled to begin. The hearing schedule will be available at the hearing. After the hearing, the hearing schedule will be placed on file in the Dockets Management Branch under Docket No. 92N–0297.

Under § 15.30(f), the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10, subpart C (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b). The transcript of the hearing will be available on the Internet at http://www.fda.gov/ohrms/dockets and orders for copies of the transcript can be placed at the meeting or through the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Any handicapped persons requiring special accommodations to attend the hearing should direct those needs to the contact person listed above.

To the extent that the conditions for the hearing, as described in this document, conflict with any provisions set out in part 15, this document acts as a waiver of those provisions as specified in § 15.30(h).

IV. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written notices of participation and comments for consideration at the hearing by October 13, 2000. To permit time after the hearing for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open following the hearing until November 20, 2000. Persons who wish to provide additional materials for consideration should file these materials with the Dockets Management Branch (address above) by November 20, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy.

Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated:
September 12, 2000

William K. Hubbard
Senior Associate
Commissioner for Policy, Planning, and Legislation

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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